as exist between the Government and the Contractor under this clause.

(j) The Government may discharge its obligations under paragraph (i) of this clause by making payments directly to subcontractors or to persons to whom the subcontractors may be liable.

(k) The rights and obligations of the parties under this clause shall survive the termination, expiration, or completion of this contract.

(End of clause)

252.235–7002 Animal welfare.

As prescribed in 235.072(a), use the following clause:

ANIMAL WELFARE (DEC 1991)

(a) The Contractor shall register its research facility with the Secretary of Agriculture in accordance with 7 U.S.C. 2316 and 9 CFR subpart C, and §2.30, and furnish evidence of such registration to the Contracting Officer before beginning work under this contract.

(b) The Contractor shall acquire animals only from dealers licensed by the Secretary of Agriculture under 7 U.S.C. 2133 and 9 CFR subpart A, §§2.1 through 2.11, or from sources that are exempt from licensing under those sections.

(c) The Contractor agrees that the care and use of animals will conform with the pertinent laws of the United States and regulations of the Department of Agriculture (see 7 U.S.C. 2131 *et seq.* and 9 CFR subchapter A, parts 1 through 4).

(d) The Contracting Officer may immediately suspend, in whole or in part, work and further payments under this contract for failure to comply with the requirements of paragraphs (a) through (c) of this clause.

(1) The suspension will stay in effect until the Contractor complies with the requirements.

(2) Failure to complete corrective action within the time specified by the Contracting Officer may result in termination of this contract and removal of the Contractor's name from the list of contractors with approved Public Health Service Welfare Assurances.

(e) The Contractor may request registration of its facility and a current listing of licensed dealers from the Regional Office of the Animal and Plant Health Inspection Service (APHIS), United States Department of Agriculture (USDA), for the region in which its research facility is located. The location of the appropriate APHIS regional office, as well as information concerning this program may be obtained by contacting the Senior Staff Officer, Animal Care Staff, USDA/APHIS, Federal Center Building, Hyattsville, MD 20782.

(f) The Contractor shall include this clause, including this paragraph (f), in all subcontracts involving research of live vertebrate animals.

(End of clause)

[56 FR 36479, July 31, 1991, as amended at 73 FR 42279, July 21, 2008]

252.235–7003 Frequency authorization.

As prescribed in 235.072(b), use the following clause:

FREQUENCY AUTHORIZATION (DEC 1991)

(a) The Contractor shall obtain authorization for radio frequencies required in support of this contract.

(b) For any experimental, developmental, or operational equipment for which the appropriate frequency allocation has not been made, the Contractor shall provide the technical operating characteristics of the proposed electromagnetic radiating device to the Contracting Officer during the initial planning, experimental, or developmental phase of contract performance.

(c) The Contracting Officer shall furnish the procedures for obtaining radio frequency authorization.

(d) The Contractor shall include this clause, including this paragraph (d), in all subcontracts requiring the development, production, construction, testing, or operation of a device for which a radio frequency authorization is required.

(End of clause)

Alternate I (AUG 2008). Substitute the following paragraph (c) for paragraph (c) of the basic clause if agency procedures authorize use of DD Form 1494, Application for Equipment Frequency Allocation:

(c) The Contractor shall use DD Form 1494, Application for Equipment Frequency Allocation, to obtain radio frequency authorization.

[56 FR 36479, July 31, 1991, as amended at 73 FR 42279, July 21, 2008]

252.235–7004 Protection of Human Subjects.

As prescribed in 235.072(e), use the following clause:

PROTECTION OF HUMAN SUBJECTS (JUL 2009)

(a) *Definitions.* As used in this clause—

(1) *Assurance of compliance* means a written assurance that an institution will comply with requirements of 32 CFR Part 219, as well as the terms of the assurance, which the

Human Research Protection Official determines to be appropriate for the research supported by the Department of Defense (DoD) component (32 CFR 219.103).

(2) *Human Research Protection Official (HRPO)* means the individual designated by the head of the applicable DoD component and identified in the component's Human Research Protection Management Plan as the official who is responsible for the oversight and execution of the requirements of this clause, although some DoD components may use a different title for this position.

(3) *Human subject* means a living individual about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual, or identifiable private information (32 CFR 219.102(f)). For example, this could include the use of human organs, tissue, and body fluids from individually identifiable living human subjects as well as graphic, written, or recorded information derived from individually identifiable living human subjects.

(4) *Institution* means any public or private entity or agency (32 CFR 219.102(b)).

(5) *Institutional Review Board (IRB)* means a board established for the purposes expressed in 32 CFR Part 219 (32 CFR 219.102(g)).

(6) *IRB approval* means the determination of the IRB that the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and Federal requirements (32 CFR 219.102(h)).

(7) *Research* means a systematic investigation, including research, development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of 32 CFR Part 219, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities (32 CFR 219.102(d)).

(b) The Contractor shall oversee the execution of the research to ensure compliance with this clause. The Contractor shall comply fully with 32 CFR Part 219 and DoD Directive 3216.02, applicable DoD component policies, 10 U.S.C. 980, and, when applicable, Food and Drug Administration policies and regulations.

(c) The Contractor shall not commence performance of research involving human subjects that is covered under 32 CFR Part 219 or that meets exemption criteria under 32 CFR 219.101(b), or expend funding on such effort, until and unless the conditions of either the following paragraph (c)(1) or (c)(2) have been met:

(1) The Contractor furnishes to the HRPO, with a copy to the Contracting Officer, an assurance of compliance and IRB approval and receives notification from the Contracting Officer that the HRPO has approved the assurance as appropriate for the research under the Statement of Work and also that the HRPO has reviewed the protocol and accepted the IRB approval for compliance with the DoD component policies. The Contractor may furnish evidence of an existing assurance of compliance for acceptance by the HRPO, if an appropriate assurance has been approved in connection with previous research. The Contractor shall notify the Contracting Officer immediately of any suspensions or terminations of the assurance.

(2) The Contractor furnishes to the HRPO, with a copy to the Contracting Officer, a determination that the human research proposed meets exemption criteria in 32 CFR 219.101(b) and receives written notification from the Contracting Officer that the exemption is determined acceptable. The determination shall include citation of the exemption category under 32 CFR 219.101(b) and a rationale statement. In the event of a disagreement regarding the Contractor's furnished exemption determination, the HRPO retains final judgment on what research activities or classes of research are covered or are exempt under the contract.

(d) DoD staff, consultants, and advisory groups may independently review and inspect the Contractor's research and research procedures involving human subjects and, based on such findings, DoD may prohibit research that presents unacceptable hazards or otherwise fails to comply with DoD procedures.

(e) Failure of the Contractor to comply with the requirements of this clause will result in the issuance of a stop-work order under Federal Acquisition Regulation clause 52.242–15 to immediately suspend, in whole or in part, work and further payment under this contract, or will result in other issuance of suspension of work and further payment for as long as determined necessary at the discretion of the Contracting Officer.

(f) The Contractor shall include the substance of this clause, including this paragraph (f), in all subcontracts that may include research involving human subjects in accordance with 32 CFR Part 219, DoD Directive 3216.02, and 10 U.S.C. 980, including research that meets exemption criteria under 32 CFR 219.101(b). This clause does not apply to subcontracts that involve only the use of cadaver materials.

(End of clause)

[74 FR 37648, July 29, 2009]